

9891 '99 JUN -3 A10:26
Dockets Management Branch (HFA-305)
Docket No. 98N-1265
Food and Drug Administration
5600 Fishers Lane
Rockville, MD. 20857

I OPPOSE THE DRAFT M.O.U. being proposed by the FDA. In particular, I OBJECT to the definition of "inordinate amount" which restricts the availability and the right to obtain medically necessary compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

Ruthanne Salento
Signature

5.29.1999
Date

COMMENTS: See letter attached.

98N-1265

Please fold, seal, and mail by June 1

C3123

May 29, 1999

To: Food and Drug Administration
Re: Docket No. 98N-1265

I am a woman, 53 years old, and I am currently using compounded medications (for hormone replacement therapy) that are shipped to me from out of state. Due to a history of breast cancer in my family--my mother and her sister both died of that disease--and also due to my doctor's advice, I cannot take the commercially produced hormone replacement therapy, since it increases the risk of breast cancer. For a long time, before I found out about natural estriol and natural progesterone, I had severe menopause symptoms of anxiety, hot flashes, depression, insomnia, nightsweats, and fatigue. I could not function and life was unbearable.

Then I found Women's Health America pharmacy, and I was able to get natural estriol and natural progesterone compounded and shipped to me. My life changed and all my symptoms went away. I now feel great and healthy.

I would like to express my personal deep wish that this precious compounded medication be available to me as long as I need it.

Please do not restrict distribution of compounded medications across state lines!!

Sincerely,

A handwritten signature in black ink, reading "Katherine Salentine". The signature is written in a cursive, flowing style with a large initial 'K' and a long, sweeping underline.

Katherine Salentine

Katherine Salentine
10 Summerhill Court
San Rafael, CA 94903



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